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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,664	05/20/2005	Jang-Ryol Liu	1628.1015	4376

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,664	Applicant(s) LIU ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-6 are pending.
2. The title of the invention is objected to because “recombinating” is not a word in the English language. Furthermore, the title is not descriptive of the instant invention as the invention involves plastid transformation. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.
3. The abstract is not descriptive of the instant invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Claim Objections

4. Claims 3 and 5 objected to because an article is missing before “16S” in line 2.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A full review of the specification indicates that nucleic acids encoding recombinases, including those from prokaryotes, are essential to the operation of the claimed invention. The claims are drawn to the use of a nucleic acid encoding any recombinase from any source.

Furthermore, claim 4 requires a recombinase gene active in a plastid". A gene comprises regulatory sequences, as well as coding sequences. The specification fails to teach any recombinase gene in which its regulatory sequences function in a plastid.

The specification fails to describe the structural features of a nucleic acid encoding any recombinase. Thus, one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus.

Hence, Applicant has not, in fact, described nucleic acids that encode recombinases. Because the sequences are not described, the method of using the sequences to transform plastids is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Word(s) appear to be missing between “which” and “the” in line 1.

Claim 1 is indefinite in its recitation of “vector ... which contains a targeting sequence for plastid” in part A. Vectors are DNA and plastid targeting sequences are proteins. Vectors do not contain proteins.

Claim 1 is indefinite in its recitation of “a nucleotide sequence of a target gene” in part C. It is unclear what this gene is a target for.

Claim 2 lacks antecedent basis for the limitation “said recombinase gene”.

Claims 3 and 5 lack antecedent basis for the limitation “said selective marker” in line 2.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3 and 5 recites the broad

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recitations “antibiotics”, and the claims also recite “spectinomycin, streptomycin, kanamycin” which is the narrower statement of the range/limitation. Claims 3 and 5 recites the broad recitations “enzyme”, and the claims also recite “cytosine deaminase, betaine aldehyde dehydrogenase” which is the narrower statement of the range/limitation.

Claims 3 and 5 are not written in proper Markush format. The claims should be in the format “selected from the group consisting of A, B, C and D.” The recitation of “and/or” in line 6 makes the claim indefinite. See MPEP § 2173.05(h).

Claims 3 and 5 are indefinite in their recitation of “and the like” in lines 5 and 6. It is not clear if the phrase is intended to further limit “antibiotics” and “enzyme” in some way.

Claim 4 states the method comprises “steps”, but only one step (a) is recited.

Claim 4 lacks antecedent basis for the limitation “said plant transformed by a recombinase gene active in a plastid” in lines 7-8.

It is not clear in claim 4 what “respectively” refers to. Generally this term is used as a shorthand when, for example, two vectors each comprises different nucleic acids. That does not appear to be the case here. Is a second vector missing from the claim?

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are those involved in producing a primary plant transformant.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staub (WO 01/29241).

The claims are drawn to a method for transforming a plant plastid, wherein the method comprises transforming a plant with a recombinase expression vector encoding any bacterial-derived recombinase operably linked to a chloroplast targeting protein plastid, then transforming the resulting transformant with a plastid transformation vector comprising a selectable marker expression cassette and a targeting sequence.

Staub teaches a method for transforming a plant plastid, wherein the method comprises transforming a plant plastid with a plastid transformation vector comprising a selectable marker expression cassette, expressing green fluorescent protein and aadA, and the Lox targeting sequence. The plant is then transformed with a recombinase expression vector encoding the bacteria-derived Cre recombinase operably linked to a chloroplast targeting protein (pg 16-27). Staub does not disclose transforming the plant with the recombinase expression vector first.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of for transforming a plant plastid as taught by Staub, to transform the plant with the recombinase expression vector first. One of ordinary skill in the art would have been motivated to do so because order of steps is an obvious design choice.

Conclusion

11. No claim is allowed.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

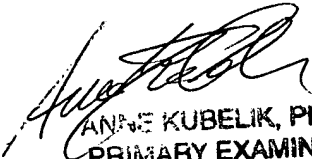
The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne Kubelik, Ph.D.
October 30, 2006



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER